US FDA grants Priority Review to Roche's Tecentriq as adjuvant treatment for certain people with early non-small cell lung cancer

- **Application is being reviewed under the US FDA's Real-Time Oncology Review pilot programme**
- **Based on results of the Phase III IMpower010 study, presented at ASCO, that showed adjuvant Tecentriq improved disease-free survival by more than one-third in PD-L1-positive early-stage lung cancer, compared with best supportive care**
- **Tecentriq is the first and only cancer immunotherapy to demonstrate positive Phase III results in the adjuvant lung cancer setting**

Basel, 3 August 2021 - Roche (SIX: RO, ROG; OTCQX: RHHBY) today announced that the US Food and Drug Administration (FDA) has accepted the company's supplemental Biologics License Application (sBLA) and granted Priority Review for Tecentriq® (atezolizumab) as adjuvant treatment following surgery and platinum-based chemotherapy for people with non-small cell lung cancer (NSCLC) whose tumours express PD-L1≥1%, as determined by an FDA-approved test. The FDA is reviewing the application under the Real-Time Oncology Review pilot programme, which aims to explore a more efficient review process to ensure safe and effective treatments are available to patients as early as possible. The FDA is expected to make a decision on approval by 1 December 2021.

"New treatment options are urgently needed in early-stage non-small cell lung cancer to help the nearly 50% of people who currently experience a recurrence following surgery," said Levi Garraway, M.D., Ph.D., Roche's Chief Medical Officer and Head of Global Product Development. "Tecentriq is the first cancer immunotherapy to show a clinically meaningful benefit in the adjuvant lung cancer setting, and we're working closely with the FDA to bring this significant advancement to patients as quickly as possible."

This application is based on disease-free survival (DFS) results from an interim analysis of the Phase III IMpower010 study, the first and only Phase III study of a cancer immunotherapy to demonstrate positive results in the adjuvant lung cancer setting. The study showed that treatment with Tecentriq, following surgery and platinum-based chemotherapy, reduced the risk of disease recurrence or death (DFS) by 34% (hazard ratio [HR]=0.66, 95% CI: 0.50-0.88) in people with Stage II-IIIA NSCLC whose tumours express PD-L1≥1%, compared with best supportive care (BSC). In this population, median DFS was not yet reached for Tecentriq compared with 35.3 months for BSC. Follow-up on the IMpower010 trial will continue with planned analyses of DFS in the overall intent-to-treat (ITT) population, including Stage IB patients, which at the time of analysis did not cross the threshold, and overall survival (OS) data, which were immature at the time of interim analysis. Safety data for Tecentriq were consistent with its known safety profile and no new safety signals were identified. Results from the IMpower010 trial were presented at the 2021 ASCO Annual Meeting.

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About the IMpower010 study
IMpower010 is a Phase III, global, multicentre, open-label, randomised study evaluating the efficacy and safety of Tecentriq compared with BSC, in participants with Stage IB-IIIA NSCLC (UICC 7th edition), following surgical resection and up to 4 cycles of adjuvant cisplatin-based chemotherapy. The study randomised 1,005 people with a ratio of 1:1 to receive either Tecentriq (up to 16 cycles) or BSC. The primary endpoint is investigator-determined DFS in the PD-L1-positive Stage II-IIIA, all randomised Stage II-IIIA and ITT Stage IB-IIIA populations. Key secondary endpoints include OS in the overall study population, ITT Stage IB-IIIA NSCLC.

About NSCLC
Lung cancer is one of the leading causes of cancer death globally. Each year 1.8 million people die as a result of the disease; this translates into more than 4,900 deaths worldwide every day. Lung cancer can be broadly divided into two major types: NSCLC and SCLC. NSCLC is the most prevalent type, accounting for around 85% of all cases. NSCLC comprises non-squamous and squamous-cell lung cancer, the squamous form of which is characterised by flat cells covering the airway surface when viewed under a microscope.

About Tecentriq
Tecentriq is a monoclonal antibody designed to bind with a protein called Programmed Death Ligand-1 (PD-L1), which is expressed on tumour cells and tumour-infiltrating immune cells, blocking its interactions with both PD-1 and B7.1 receptors. By inhibiting PD-L1, Tecentriq may enable the activation of T-cells. Tecentriq is a cancer immunotherapy that has the potential to be used as a foundational combination partner with other immunotherapies, targeted medicines and various chemotherapies across a broad range of cancers. The development of Tecentriq and its clinical programme is based on our greater understanding of how the immune system interacts with tumours and how harnessing a person's immune system combats cancer more effectively.

Tecentriq is approved in the US, EU and countries around the world, either alone or in combination with targeted therapies and/or chemotherapies in various forms of NSCLC, SCLC, certain types of metastatic urothelial cancer, in PD-L1-positive metastatic triple-negative breast cancer and for hepatocellular carcinoma. In the US, Tecentriq is also approved in combination with Cotellic® (cobimetinib) and Zelboraf® (vemurafenib) for the treatment of people with BRAF V600 mutation-positive advanced melanoma.

About Roche in cancer immunotherapy
Roche's rigorous pursuit of groundbreaking science has contributed to major therapeutic and diagnostic advances in oncology over the last 50 years, and today, realising the full potential of cancer immunotherapy is a major area of focus. With over 20 molecules in development, Roche is investigating the potential benefits of immunotherapy alone, and in combination with chemotherapy, targeted therapies or other immunotherapies

with the goal of providing each person with a treatment tailored to harness their own unique immune system to attack their cancer. Our scientific expertise, coupled with innovative pipeline and extensive partnerships, gives us the confidence to continue pursuing the vision of finding a cure for cancer by ensuring the right treatment for the right patient at the right time.

In addition to Roche's approved PD-L1 checkpoint inhibitor, Tecentriq® (atezolizumab), Roche's broad cancer immunotherapy pipeline includes other checkpoint inhibitors, such as tiragolumab, a novel cancer immunotherapy designed to bind to TIGIT, individualised neoantigen therapies and T-cell bispecific antibodies.

To learn more about Roche's scientific-led approach to cancer immunotherapy, please follow this link: http://www.roche.com/research_and_development/what_we_are_working_on/oncology/cancer-immunotherapy.htm

About Roche
Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people's lives. The combined strengths of pharmaceuticals and diagnostics, as well as growing capabilities in the area of data-driven medical insights help Roche deliver truly personalised healthcare. Roche is working with partners across the healthcare sector to provide the best care for each person.

Roche is the world's largest biotech company, with truly differentiated medicines in oncology, immunology, infectious diseases, ophthalmology and diseases of the central nervous system. Roche is also the world leader in in vitro diagnostics and tissue-based cancer diagnostics, and a frontrunner in diabetes management. In recent years, Roche has invested in genomic profiling and real-world data partnerships and has become an industry-leading partner for medical insights.

Founded in 1896, Roche continues to search for better ways to prevent, diagnose and treat diseases and make a sustainable contribution to society. The company also aims to improve patient access to medical innovations by working with all relevant stakeholders. More than thirty medicines developed by Roche are included in the World Health Organization Model Lists of Essential Medicines, among them life-saving antibiotics, antimalarials and cancer medicines. Moreover, for the twelfth consecutive year, Roche has been recognised as one of the most sustainable companies in the Pharmaceuticals Industry by the Dow Jones Sustainability Indices (DJSI).

The Roche Group, headquartered in Basel, Switzerland, is active in over 100 countries and in 2020 employed more than 100,000 people worldwide. In 2020, Roche invested CHF 12.2 billion in R&D and posted sales of CHF 58.3 billion. Genentech, in the United States, is a wholly owned member of the Roche Group. Roche is

the majority shareholder in Chugai Pharmaceutical, Japan. For more information, please visit www.roche.com.

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